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Date: 01/23/2006

Sean Mellino

Sean Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Markus Krumme
Serial No. : 10/533,835 / Confirmation No. 8149
Filing Date : May 4, 2005
Examiner (Group Art Unit) : ___ / Art Unit 1616
Title : MULTILAYERED TRANSMUCOSAL
THERAPEUTIC SYSTEM
Attorney File : RO4037US (#90568)

Commissioner for Patents
P O Box 1450
Alexandria, Virginia, 22313-1450

LETTER

Dear Sir:

In order to supplement the filing documents of the above-referenced U.S. national phase patent application, enclosed herewith is a translation of the International Preliminary Examination Report (PCT/IPEA/409).

Respectfully submitted,

Date: 01/23/2006

Enc.

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PATENT COOPERATION TREATY

PCT/EP2003/012272



Translation

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LTS 2002/007 PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2003/012272	International filing date (day/month/year) 04 November 2003 (04.11.2003)	Priority date (day/month/year) 13 November 2002 (13.11.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/00		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG et al.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 10 March 2004 (10.03.2004)	Date of completion of this report 07 March 2005 (07.03.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2003/012272

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☒ the description:
- pages _____ 1-14 _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ 1-17 _____ received by this Authority on _____ 15 February 2005 (15.02.2005)
- pages* _____ received by this Authority on _____
- ☒ the drawings:
- pages _____ 1/1 _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/12272

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Non-establishment of opinion with regard to novelty,
inventive step and industrial applicability

Claims 16 and 17 relate to a subject matter which, in the opinion of the Examining Authority, falls under PCT Rule 67.1(iv). Consequently, no opinion is established with regard to the industrial applicability of this subject matter (PCT Article 34(4)(a)(i)).

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/12272

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-17	YES
	Claims		NO
Inventive step (IS)	Claims	1-17	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims		NO

2. Citations and explanations

1. The film-like therapeutic system according to the main claim 1 differs from the cited prior art in that it has a backing layer based on polyacrylates, which serves as an active ingredient reservoir, and an insoluble mucoadhesive layer based on polyvinyl alcohol(s). Document WO99/55312 and Solomonidou D. et al. disclose the use of polyvinyl alcohol as a film-forming polymer in the structure of a mucoadhesive layer. However, neither one of these documents uses a backing layer based on polyacrylates. A backing layer based on polyacrylates is known, for example from document US2002/0142036 (see paragraphs [0013-0014]). However, the combination with a mucoadhesive layer on a polyvinyl alcohol basis is not disclosed therein. The remaining search report citations disclose neither the backing layer based on polyacrylates nor the mucoadhesive layer based on polyvinyl alcohol(s). The subject matter of claim 1 is therefore novel (PCT Article 33(2)).

2. In the light of the prior art, the problem to be solved is that of providing an alternative mucoadhesive therapeutic system, which is insoluble

or poorly soluble and accordingly permits the slow release of the active substance. The cited prior art offers nothing to suggest that a mucoadhesive layer produced on the basis of polyvinyl alcohol and having a backing layer based on polyacrylate can be joined into a single advantageous system. The system defined in claim 1 therefore also involves an inventive step (PCT Article 33(3)) because it is not considered an obvious alternative to the prior art.

3. Claims 2-15 are dependent on claim 1 and therefore likewise meet the PCT requirements for novelty and inventive step.

Similarly, the use of the therapeutic system according to claims 1-15 defined in claims 16 and 17 is likewise novel and inventive.

4. The subject matter of claims 1-15 is considered industrially applicable and therefore likewise meets the requirements of PCT Article 33(4).